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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,599	10/03/2000	Leigh T Canham	124-796	1219
23117	7590	09/20/2006	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 167, 172 and 177 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 167, 172 and 177 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Receipt is acknowledged of the request for continued examination filed 07/14/2006.

The following is a new rejection of the claims:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 167, 172 and 177 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mesoporous silicon implant which is obtained by heating and oxidizing the impregnate substance (bioactive), does not reasonably provide enablement for heating and oxidizing the porous silicon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification clearly states at page 12, lines 1-12, that it is the impregnate, not the porous silicon which is heated and oxidized. Appropriate correction is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 177 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO'101.

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. Tissue compatibility although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be considered a new characteristic of a known material. The amount of drug distributed through the implant as well as the amount of resorption are dependent upon the material and its porosity. Since the reference discloses both, both of these parameters are inherent to the material selected. The WO'101 reference is silent as to the method of reacting it with an oxidizing agent. However, applicant defines the silicon implant as not necessarily "pure silicon" at page 9, lines 1-10. As stated there, since silicon in general works, any silicon-based compound which has similar corrosion properties and is not harmful can read in the claimed silicon product.

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As such, the silicon product of WO'101 falls well within this definition. As such, the ordinary practitioner would have expected similar therapeutic results from the method of delivering using the porous silicon of WO'101. The instant claim would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of WO'101.

The following rejection is maintained in this action:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 167, 172 are rejected under 35 U.S.C. 102(b) as being anticipated by WO'97/06101 (WO'101).

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. Tissue compatibility although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be

considered a new characteristic of a known material. The amount of drug distributed through the implant as well as the amount of resorption are dependent upon the material and its porosity. Since the reference discloses both, both of these parameters are inherent to the material selected. While reference does not address reaction with an oxidant, the method of making does not lend the product patentable weight if the product itself is anticipated. The instant claims are anticipated by WO'101.

### ***Response to Arguments***

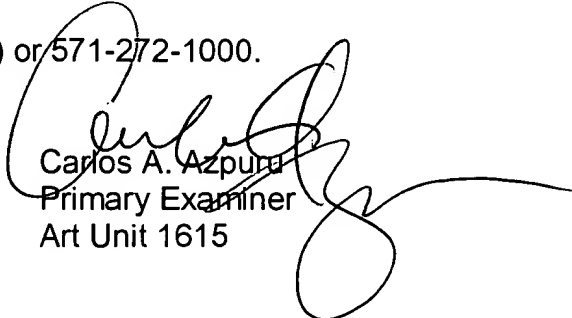
Applicant's arguments filed 07/14/2006 have been fully considered but they are not persuasive.

Applicant argues that because the silicon implant of the reference is not heated and reacted with an oxidizing agent, it does not anticipate the implant claims. However, applicant is reminded that even if the method of making the product in a product by process claim is different, it is the final product which determines patentability. Even if the silicon of the reference is not pure silicon, applicants broadly define the silicon product as including any silicon with similar corrosive properties that is still biocompatible (see page 9, lines 1-10). As such, the instant claims are anticipated by WO'101.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

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